SECTION 2.0 SUMMARY OF THE BASIS FOR SUBSTANTIAL EQUIVALENCE

MAY 2 3 2006

510(k) Summary

Submitter:

Future Mobility HealthCare Inc.
2775 Slough Street
Mississauga, ON, L4T 1G2 Tel. (1-888-737-4011)

Contact:
Mr. William Salter
Toll Free: 1-888-737-4011, Local: 905-671-1661
wtsalter@future-mobility.com

Date: December 12, 2005

Trade Name: Orion II Tilt-in-space wheelchair

Common Name: Wheelchair

Classification Name: Wheelchair, Mechanical

Predicate Devices:

We are making the claim that the Future Mobility Orion II is substantial equivalent to the predicated device listed in the chart below.

LEGALLY MARKETED PREDICATE DEVICE	MANUFACTURE NAME	REGULATORY CLASS AND PRODUCT CODE	510(K) REGISTRATION NUMBER
Concept 45	INVACARE CORP.	Class I/IOR	K951138

The rationale of declaring the new Future Mobility HealthCare Orion II is substantial equivalent to the above predicate device is based on the following:

- ✓ Same Indications for use: providing mobility to persons limited to a sitting position.
- ✓ Similar key design technical characteristics- The Invacare Concept 45 Medical device and the Orion II are mechanical wheelchairs which have technical similarities such as a tilt, and recline capabilities. Both devices contain an adjustable back angle and provide similar seat depth and widths.
- ✓ Similar size, weight, and performance.

Description:

The Future Mobility HealthCare Orion II wheelchair is a compact tilt-in-space wheelchair offering 45° of tilt, 30° of recline and adjustable seat-to-floor heights of 12 ¾" to 19". It consists of rigid, mechanical, steel frame and upholstery that meets the California Technical Bulletin CAL 117 standard for flame retardant. It has two rear wheels (12", 20", 22" or 24" in diameter) and two front casters (4", 5", 7" or 8" in diameter) for turning and maneuverability.

Indications for Use:

The Orion II is indicated for providing mobility to persons limited to a sitting position.

Technological Comparison to the Predicate:

Technologically, the Future Mobility HealthCare Orion II wheelchair is substantially equivalent to the Invacare Concept 45 wheelchair. Both devices are compact tilt-n-space chairs which have the same indicated intended use with at least a 45 degree tilt and 30 degree recline option. Both material used are resistance- ignitability fabric and also meets the California Technical Bulletin CAL 117 standard for flame retardant. The risks, safety or effectiveness and benefits for the Future Mobility HealthCare Orion II are also comparable. The table of Comparison in Section 6.1 will provide additional information illustrating that the new Future Mobility HealthCare Orion II wheelchair is substantially equivalent to the Invacare Concept 45 wheelchair.

Conclusion:

Future Mobility HealthCare Orion II wheelchair was developed based on the standard ANSI/RESNA Wheelchair Vol.1 which involves ISO 7176. It is the conclusion that the Future Mobility HealthCare ORION II is safe and effective, as well as substantially equivalent to the device identified as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2006

Future Mobility HealthCare, Inc.
% Mr. William Salter
President & CEO
2775 Slough Street
Mississauga, Ontario, L4T 1G2

Re: K061010
Trade/Device Name: Future Mobility HealthCare Inc. Orion II Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: April 6, 2006
Received: April 12, 2006

Dear Mr. Salter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061010

Device Name: Future Mobility HealthCare Inc. Orion II Wheelchair

Indications for Use:

The Future Mobility HealthCare Inc. Orion II Wheelchair is intended to provide mobility to persons limited to a sitting position.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061010